PATENT COOPERATION TREATY

COPY

PCT

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

CASEY, Lindsay J.
F.R. KELLY & CO.
27 Clyde Road
Ballsbridge
Dublin 4
IRLANDE

WRITTEN OPINION
(PCT Rule 66)

Date of mailing *(day/month/year)*	03.09.2004
Applicant's or agent's file reference: P68878PC00	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IB 03/06399	05.12.2003	05.12.2002

International Patent Classification (IPC) or both national classification and IPC
A61B5/053

Applicant
UNIVERSITY OF ULSTER et al

1. This written opinion is the **second** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 05.04.2005

RECEIVED
06 SEP 2004

COMPUTER GENERATED
Date: 6/9/04

Name and mailing address of the international preliminary examining authority:

European Patent Office - Gitschiner Str 103
D-10958 Berlin
Tel +49 30 25901 - 0
Fax: +49 30 25901 - 840

Authorized Officer
TRACHTERNA, M

Formalities officer (incl extension of time limits)
Koster, A
Telephone No +49 30 25901-726

I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-14 as originally filed

Claims, Numbers

1-27 as originally filed

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-27
Inventive step (IS)	Claims	1-27
Industrial applicability (IA)	Claims	1-27

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

   D1: LACKERMEIER A H ET AL: 'IN VIVO AC IMPEDANCE SPECTROSCOPY OF HUMAN SKIN' ANNALS OF THE NEW YORK ACADEMY OF SCIENCES, NY, US, vol. 873, 20 April 1999, pages 197-213, XP008029774, ISSN: 0077-8923
   D2: US 2002/082668 A1 (INGMAN DOV) 27 June 2002
   D3: US-A-5 184 620 (CUDAHY MICHAEL J ET AL) 9 February 1993

2. The present application does not meet the requirements of Article 33(2) PCT, because the subject-matter of claims 1-4, 6-12, 15, 16, 18-25 is not new.

2.1 The document D1 discloses (the references in parentheses applying to this document): a tissue mapping system (p. 206/l. 15-17) comprising:
- a set of test electrodes (p. 208/l. 7-13, fig. 7) for application to the surface of tissue under investigation; and
- circuit means (p. 206/l. 20 - p. 207/l. 1; fig. 6) for measuring an electrical characteristic of the tissue underlying each test electrode.

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).

2.2 For the same reasons as stated above the corresponding method of claim 18 is also not new.

2.3 The additional features of dependent claims 2-4, 7-12, 15, 16, 19-25 are also known from D1:

cls. 2, 3, 19:	p. 208/l. 8-11; fig. 7
cls. 4, 20:	p. 211/l. 6-8
cls. 7, 21:	fig. 6 (computer))
cls. 8, 22:	p. 206/l. 20-22
cls. 9, 23:	p. 210/l. 32-36 and p. 209/l. 4-6, fig. 4 (indifferent electrode)
cls. 10, 24:	p. 204/l. 1-6, fig 4 (test and sense electrodes)
cls. 11,12:	p. 209/l. 1-4, fig. 7 (sense electrode)
cls. 15,16,25:	p. 210/l. 32-36

2.4 It is noted that the objection of lack of novelty for claims 1- 4, 6, 8, 18-20, 22 set out above could also have been substantiated on document D3 (col. 5/l. 43-45, 52-53; col. 5/l. 67 - col. 6/l. 7; col. 7/l. 7-19; fig. 1 (10, 11, 12, 40)).

3. The present application does not meet the requirements of Article 33(3) PCT, because the subject-matter of claims 6, 7, 13, 14, 17, 26, 27 is not inventive.

3.1 The apparatus disclosed in document D1 differs from the subject-matter of claim 27 in that it is not incorporated in a wound dressing.

The problem to be solved by the present invention may therefore be regarded as to map a skin wound without affecting the healing process.

Document D1 mentions the application of the disclosed apparatus to tissue injury (p. 212/l. 12-15). As the apparatus disclosed in D1 is specially adapted to perform mapping of the skin it is implicit that said tissue injury corresponds to a wound of the skin. It is self-evident to the person skilled in the art, that the risk of injury or infection (as it would result from the assessment of a wound by therapeutic or diagnostic devices) has to be minimized. It would therefore be obvious to incorporate the apparatus of D1 in a wound dressing especially as the incorporation of electrodes into a wound dressing has already been employed for the same purpose in a similar device (D2: paragraph 147).

Moreover, as it is also mentioned in the description of the present application (p. 12/l.14-18), it is pointed out that such an electrode arrangement does not provide any features which are specific for electrotherapy or the measurement of an electrical characteristic (see also D3: col. 1/l. 6-9). Consequently, when confronted with the problem of mapping a skin wound without affecting the healing process, the skilled person would realize that the device described in document D2 provides an effective solution.

Therefore, claim 27 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT).

3.2 For the same reasons as stated under 3.1 the subject-matter of dependent claim 17 and of the corresponding method claim 26 is not inventive.

3.3 Dependent claims 5, 6, 13, 14 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to inventive step (Art. 33(3) PCT).

The use of hydrogel (claim 5) as well as insulated leads (claim 6) and the arrangement of electrodes on the flexible backing material (claim 14) are considered to come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen.

Impedance measurement by means of a given test electrode and an adjacent test electrode which acts temporarily as its reference electrode (claim 13) is extensively used in bipolar impedance recordings (see also D1: p. 203/l. 7-9). Therefore, it would be obvious to the person skilled in the art to apply this feature.

4. The industrial applicability (Art. 33(4) PCT) is clearly given for the subject-matter of all apparatus claims. However, it is noted that no unified criteria exists as regards industrial applicability of diagnostic methods. If the method claims are maintained, this issue will therefore be the subject of further examination in a later regional/national phase.

5. If amendments are filed, the Applicant must comply with the requirements of Rule 66.8 PCT and indicate the basis in the originally filed application of the amendments made (Article 34(2)(b) PCT) otherwise these amendments will not be taken into consideration for the establishment of international preliminary examination.

Claims

1. A tissue mapping system comprising a two-dimensional array of test electrodes for application to the surface of tissue under investigation, circuit means for measuring an electrical characteristic of the tissue underlying each test electrode, and a display device providing a visual map of the tissue based upon the measured electrical characteristics.

2. A system as claimed in claim 1, wherein the array of test electrodes is arranged on a flexible backing of insulating material.

3. A system as claimed in claim 2, wherein the array of electrodes is a rectangular array.

4. A system as claimed in claim 2 or 3, wherein each test electrode is covered with a conductive gel, the resistance between adjacent test electrodes being high relative to the resistance via the gel between each test electrode and the underlying tissue.

5. A system as claimed in claim 4, wherein the gel is hydrogel.

6. A system as claimed in any one of claims 2 to 5, wherein leads for the test electrodes are also disposed on the flexible backing of insulating material and covered with an insulating material.

7. A system as claimed in any preceding claim, wherein the two-dimensional array comprises at least 25 test electrodes.

8. A system as claimed in any preceding claim, wherein the electrical characteristic is the impedance of the tissue underlying each test electrode.

9. A system as claimed in any preceding claim, wherein the circuit means measures the electrical characteristic by applying an alternating electrical signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part.

10. A system as claimed in claim 9, wherein the circuit means measures the electrical characteristic by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.

11. A system as claimed in claim 10, wherein the reference electrode is also disposed on the flexible backing of insulating material.

12. A system as claimed in claim 11, wherein a single reference electrode is common to a plurality of test electrodes.

13. A system as claimed in claim 11, wherein during measurement on a given test electrode an adjacent test electrode acts temporarily as its reference electrode.

14. A system as claimed in any one of claims 9 to 13, wherein the said at least one other electrode is also disposed on the flexible backing of insulating material.

15. A system as claimed in any one of claims 9 to 14, wherein for each test electrode a measurement is made at a plurality of different frequencies.

16. A system as claimed in any one of claims 9 to 15, wherein the or each measurement is made at a frequency of from 1 milliHz to 100 kHz, preferably from 1 Hz to 50 kHz.

17. A system as claimed in any preceding claim, wherein the array of test electrodes is incorporated into a wound dressing.

18. A method of mapping tissue comprising applying a two-dimensional array of test electrodes to the surface of tissue under investigation, measuring an electrical characteristic of the tissue underlying each test electrode, and displaying a visual map of the tissue based upon the measured electrical characteristics.

19. A method as claimed in claim 18, wherein the array of test electrodes is arranged on a flexible backing of insulating material.

20. A method as claimed in claim 19, wherein each test electrode is covered with a conductive gel, the resistance between adjacent test electrodes being

high relative to the resistance via the gel between each test electrode and the underlying tissue.

21. A method as claimed in any one of claims 18 to 20, wherein the two-dimensional array comprises at least 25 test electrodes.

22. A method as claimed in any one of claims 18 to 21, wherein the electrical characteristic is the impedance of the tissue underlying each test electrode.

23. A method as claimed in any one of claims 18 to 22, wherein the electrical characteristic is measured by applying an alternating electrical signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part.

24. A method as claimed in claim 23, wherein the electrical characteristic is measured by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.

25. A method as claimed in claim 23 or 24, wherein for each test electrode a measurement is made at a plurality of different frequencies.

26. A method as claimed in any one of claims 18 to 25, wherein the array of test electrodes is incorporated into a wound dressing and applied to a wound.

Claims

1. A tissue mapping system comprising a ~~set~~ two-dimensional array of test electrodes for application to the surface of tissue under investigation, ~~and~~ circuit means for measuring an electrical characteristic of the tissue underlying each test electrode, and a display device providing a visual map of the tissue based upon the measured electrical characteristics.

2. A system as claimed in claim 1, wherein the ~~set~~ array of test electrodes is arranged on a flexible backing of insulating material.

3. A system as claimed in claim 2, wherein the ~~set of electrodes comprises a two-dimensional~~ array of electrodes~~, preferably~~ is a rectangular array.

4. A system as claimed in claim 2 or 3, wherein each test electrode is covered with a conductive gel, the resistance between adjacent test electrodes being high relative to the resistance via the gel between each test electrode and the underlying tissue.

5. A system as claimed in claim 4, wherein the gel is hydrogel.

6. A system as claimed in any one of claims 2 to 5, wherein leads for the test electrodes are also disposed on the flexible backing of insulating material and covered with an insulating material.

7. A system as claimed in any preceding claim, ~~further including means for displaying said measured characteristics and/or derivative(s) thereof in human readable form~~ wherein the two-dimensional array comprises at least 25 test electrodes.

8. A system as claimed in any preceding claim, wherein the electrical characteristic is the impedance of the tissue underlying each test electrode.

9. A system as claimed in any preceding claim, wherein the circuit means measures the electrical characteristic by applying an alternating electrical signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part.

10. A system as claimed in claim 9, wherein the circuit means measures the electrical characteristic by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.

11. A system as claimed in claim 10, wherein the reference electrode is also disposed on the flexible backing of insulating material.

12. A system as claimed in claim 11, wherein a single reference electrode is common to a plurality of test electrodes.

13. A system as claimed in claim 11, wherein during measurement on a given test electrode an adjacent

test electrode acts temporarily as its reference electrode.

14. A system as claimed in any one of claims 9 to 13, wherein the said at least one other electrode is also disposed on the flexible backing of insulating material.

15. A system as claimed in any one of claims 9 to 14, wherein for each test electrode a measurement is made at a plurality of different frequencies.

16. A system as claimed in any one of claims 9 to 15, wherein the or each measurement is made at a frequency of from 1 milliHz to 100 kHz, preferably from 1 Hz to 50 kHz.

17. A system as claimed in any preceding claim, wherein the ~~set~~ array of test electrodes is incorporated into a wound dressing.

18. A method of mapping tissue comprising applying a ~~set~~ two-dimensional array of test electrodes to the surface of tissue under investigation, ~~and~~ measuring an electrical characteristic of the tissue underlying each test electrode, and displaying a visual map of the tissue based upon the measured electrical characteristics.

19. A method as claimed in claim 18, wherein the ~~set~~ array of test electrodes is arranged ~~in a two-dimensional array~~ on a flexible backing of insulating material.

20. A method as claimed in claim 19, wherein each test electrode is covered with a conductive gel, the resistance between adjacent test electrodes being high relative to the resistance via the gel between each test electrode and the underlying tissue.

21. A method as claimed in any one of claims 18 to 20, ~~further including displaying said measured characteristics and/or derivative(s) thereof in human readable form~~ wherein the two-dimensional array comprises at least 25 test electrodes.

22. A method as claimed in any one of claims 18 to 21, wherein the electrical characteristic is the impedance of the tissue underlying each test electrode.

23. A method as claimed in any one of claims 18 to 22, wherein the electrical characteristic is measured by applying an alternating electrical signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part.

24. A method as claimed in claim 23, wherein the electrical characteristic is measured by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.

25. A method as claimed in claim 23 or 24, wherein for each test electrode a measurement is made at a plurality of different frequencies.

26. A method as claimed in any one of claims 18 to 25, wherein the ~~set~~ array of test electrodes is incorporated into a wound dressing and applied to a wound.

~~27. A wound dressing incorporating a set of test electrodes for application to the surface of wound tissue and circuit means for measuring an electrical characteristic of the tissue underlying each test electrode.~~